Appendix: Claims On Appeal

33. (previously presented) A pharmaceutical composition comprising:

(a) a first intraoral portion which rapidly dissolves or disintegrates intraorally to release a therapeutically effective amount of at least one pharmaceutically active ingredient which is absorbed sublingually in a therapeutically effective level,

the active ingredient selected from the group consisting of Buprenorphine, Parecoxib, Aceclofenac, Buspirone, Ipsapirone, Fexofenadine, Loratadine, Dexbrompheniramine, Temelastine, Verapamil, Amlodipine, Ergotamine Tartrate, Dihydroergotamine, Ondansetron, Prochlorperazine, Sildenafil, Alprostadil, Sufentanil, Lofentanil, Carfentanil, Nalbuphine, Droperidol, and Haloperidol, being present in an amount between 1 micrograms and 50 mg, and having a rapid onset following intraoral administration; and

(b) a second oral portion located within the first portion which is released into the gastrointestinal tract in a therapeutically effective amount after the intraoral portion has disintegrated or dissolved, wherein the second portion is either a sustained release or chewable formulation.

34. (previously presented) The pharmaceutical composition of claim 33 wherein the active ingredient of the intraoral component undergoes first pass metabolism.

35. (Original) The pharmaceutical composition of claim 33 in a tablet or capsule unit dosage form.

36. (Original) The pharmaceutical composition of claim 35 wherein the unit dosage form is a tablet and the second oral portion of the composition is an inner core of the tablet surrounded by an outer coating of the first intraoral component.

37. (Original) The pharmaceutical composition of claim 35 wherein the unit dosage form is a multi-layer tablet wherein the second oral portion of the composition comprises one or more inner layers of the tablet and the first intraoral component comprises one or more of the outer layers of the multi-layer tablet.

38. (Original) The pharmaceutical composition of claim 36 wherein the outer coating is a film coat that is applied as a layer to the inner core.

39. (Original) The pharmaceutical composition of claim 36 wherein the outer coating is a compression coat that is compressed around the inner core.

40. (Original) The pharmaceutical composition of claim 33 comprising an outer film coating comprising at least one pharmaceutically acceptable coating polymer selected from the group consisting of cellulose, hydroxypropyl methylcellulose, methyl cellulose, polyvinylpyrrolidone, and polyethylene glycol, a pharmaceutically acceptable plasticizer, a pharmaceutically acceptable glidant and a pharmaceutically acceptable colorant.

41. (previously presented) A pharmaceutical composition comprising:

(a) a first intraoral portion which rapidly dissolves or disintegrates intraorally to release a therapeutically effective amount of at least one pharmaceutically active ingredient which is absorbed sublingually in a therapeutically effective level,

the active ingredient having a molecular weight not exceeding 350 daltons or an active ingredient selected from the group consisting of Buprenorphine, Parecoxib, Aceclofenac, Buspirone, Ipsapirone, Fexofenadine, Loratadine, Dexbrompheniramine, Temelastine, Verapamil, Amlodipine, Ergotamine Tartrate, Dihydroergotamine, Ondansetron, Prochlorperazine, Sildenafil, Alprostadil, Sufentanil, Lofentanil,

Carfentanil, Nalbuphine, Droperidol, and Haloperidol, being present in an amount between 1 micrograms and 50 mg, and having a rapid onset following intraoral administration, and

the first intraoral portion comprising a pharmaceutically acceptable effervescent agent which generates effervescence when contacted with salivary fluid; and

(b) a second oral portion located within the first portion which is released into the gastrointestinal tract in a therapeutically effective amount after the intraoral portion has disintegrated or dissolved.

42. (Original) The pharmaceutical composition of claim 33 comprising a pharmaceutically acceptable flavoring agent in the first intraoral component.

43. (Original) The pharmaceutical composition of claim 33 wherein the second oral component is in a sustained release formulation.

44. (Original) The pharmaceutical composition of claim 43 wherein the sustained release is over a period of 0.5 to 24 hours.

45. (Original) The pharmaceutical composition of claim 33 comprising a delayed release coating.

46. (Original) The pharmaceutical composition of claim 45 wherein release is delayed for a period of 0.5 to 12 hours.

47. (Original) The pharmaceutical composition of claim 33 wherein the second oral component is chewable and comprises at least one pharmaceutically acceptable excipient suitable for a chewable medication and a flavoring agent.

48. (Original) The pharmaceutical composition of claim 33 wherein the first intraoral component disintegrates or dissolves within 10 minutes, when the composition is contacted with saliva during intraoral administration.

49. (Original) The pharmaceutical composition of claim 33 wherein the second oral component remains intact until the intraoral administration of the first intraoral component has been delivered.

50. (Original) The pharmaceutical composition of claim 33 further comprising a pharmaceutically acceptable signaling system located between the first intraoral component and the second oral component that is detectable by the patient upon substantial release of the pharmaceutically active ingredient in the first intraoral component.

51. (previously presented) The pharmaceutical composition of claim 41 wherein the pharmaceutically active ingredient in the first intraoral component is selected from the group consisting of analgesics, antihistamines, antidiarrheals, anxiolytics, hypnotics, stimulants, cardiovascular drugs, pulmonary drugs, anti-hypertensives, anti-emetics, anti-inflammatory drugs, renal drugs, steroids, drugs for neurological disorders, anti-psychotic drugs, drugs for treating endocrine disorders, drugs for promoting immune response, drugs for treating osteoarthritis, drugs for treating glaucoma, drugs for treating allergic rhinitis, drugs for treating anemias and other hematological disorders, drugs for treating infectious diseases, drugs for the treatment and symptoms of cancer, drugs for insomnia, and antidiabetic drugs.

52. (Original) The pharmaceutical composition of claim 33 wherein the active ingredient in the first intraoral composition has a lower bioavailability upon oral administration when compared to intravenous administration.

53. (Original) The pharmaceutical composition of claim 33 wherein the active ingredient in the first intraoral composition is in a dosage of between 10 micrograms and 30 mg.

54. (previously presented) The pharmaceutical composition of claim 41 wherein the active ingredient has a molecular weight of less than 350 Daltons.

55. (previously presented) A process for the preparation of a pharmaceutical composition in unit dosage

(a) a first intraoral portion which rapidly dissolves or disintegrates intraorally to release a therapeutically effective amount of at least one pharmaceutically active ingredient which is absorbed sublingually in a therapeutically effective level,

the active ingredient selected from the group consisting of Buprenorphine, Parecoxib, Aceclofenac, Buspirone, Ipsapirone, Fexofenadine, Loratadine, Dexbrompheniramine, Temelastine, Verapamil, Amlodipine, Ergotamine Tartrate, Dihydroergotamine, Ondansetron, Prochlorperazine, Sildenafil, Alprostadil, Sufentanil, Lofentanil, Carfentanil, Nalbuphine, Droperidol, and Haloperidol, being present in an amount between 1 micrograms and 50 mg, and having a rapid onset following intraoral administration; and

(b) a second oral portion located within the first portion which is released into the gastrointestinal tract in a therapeutically effective amount after the intraoral portion has disintegrated or dissolved.

which comprises the steps of:

(i) providing the second oral component as an inner tablet core or as at least one layer of a multi-layer tablet core or as an uncoated capsule, wherein the second oral component is either a sustained release or chewable formulation; and

(ii) applying the first intraoral component as an outer layer or as several outer layers forming an outer coating on the first portion.

56. (Original) The process of claim 55 wherein the active ingredient exhibits first pass metabolism.

57. (Original) The process of claim 55 wherein the active ingredient has a molecular weight of less than 350 daltons.

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